JAN 18 2006

K060003

Appendix 1

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory

   Model Name: MRT-1503/P5

   Trade/Proprietary Name: EXCELART Vantage™ ZGV

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **U.S. Agent Name and Address:** TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
   2441 MICHELLE DRIVE
   TUSTIN, CA 92780

   Contact Person: Paul Biggins
   (714) 730 - 5000

4. **Manufacturing Site:** TOSHIBA CORPORATION
   MEDICAL SYSTEMS COMPANY
   1385 Shimoishigami
   Otawara-shi, Tochigi 324-8550, Japan

5. **DATE OF SUBMISSION:** December 22, 2005

6. **DEVICE DESCRIPTION**

The EXCELART Vantage™ ZGV system is comparable to the current EXCELART Vantage™ XGV/AGV system; with the following exceptions.

- The maximum gradient strength and the maximum slew rate have been increased.
- The clock of CPU of computer system was increased from 2.8GHz to 3.2GHz.
- SAR 1st level operating mode as specified in IEC 60601-2-33 (2002).
- Thel performance (Min.TR/Min.TE / Min.Slice thickness) of a sequence has been improved.

Model Number with suffix	Trade/Proprietary Name
MRT-1503/P5	EXCELART Vantage™ ZGV

6.1. SUMMARY OF MAJOR HARDWARE CHANGES

A. The gradient coil was changed for higher gradient strength and slew rate .

B. The gradient power supply was changed for higher gradient strength and slew rate.

C: The clock of CPU was changed from 2.8GHz to 3.2GHz.

D. Flex coils (70, 100, 150, 200mm, Rectangular) are added to the available coil list.

E. QD Knee/Foot coil (K051763) is added.

6.2. SUMMARY OF MAJOR SOFTWARE CHANGES

A. New CPU correspondence.

B. New RF coil control.

C. SAR limitation control.

7. SAFETY PARAMETERS

	Current EXCELART Vantage™ XGV/AGV (No changes from the previous submission, K032490)	New EXCELART Vantage™ ZGV
a. Static field strength:	1.5 T	Same
b. Peak and A-weighted acoustic noise:	110 dB (A-weighted)	Same
c. Operational modes:	1st operating mode for dB/dt	1st operating mode for dB/dt and SAR
i. Safety parameter display:	SAR, dB/dt	Same
ii. Operating mode access requirements:	Not applicable because used only in normal operating mode	Allows access to 1st level operating mode
d. Maximum SAR	Normal operating mode specified in IEC 60601-2-33 (2002)	1st operating mode specified in IEC 60601-2-33 (2002)
e. Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2002)	Same
and Gradient coil dimensions:	692 x 893 x 1405 (unit: mm)	Same
f. Potential emergency conditions and means provided for shutdown:	Shut down by Emergency Ramp Down Unit for collision hazard by ferromagnetic objects	Same
g. Biocompatibility of materials:	Not applicable	Same

8. IMAGING PERFORMANCE PARAMETERS

No changes from the previous submission, K032490 .

9. INTENDED USE

No changes from the previous submission, K032490 .

10. EQUIVALENCY INFORMATION

TOSHIBA Medical Systems Corporation believes that the new EXCELART Vantage™ ZGV (model MRT-1503/P5) Magnetic Resonance Imaging (MRI) system is substantially equivalent to the current EXCELART Vantage™ XGV/AGV (model MRT-1503/P3, MRT-1503/P2) (K032490) cleared on August 21, 2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K060003
Trade/Device Name: Excelart Vantage™ ZGV
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 29, 2005
Received: January 3, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1

Indications for Use

510(k) Number (if known): K060003

Device Name: EXCELART Vantage™ ZGV

Indications for Use:

Imaging of:

- The Whole Body (including head, abdomen, pelvis, limbs and extremities, spine, neck, TMJ, heart, blood vessels). [Application terms include MRCP (MR Cholangiopancreatography), MR Cisternography, MR Urography, MR Myelography, MR Fluoroscopy, SAS (Surface Anatomy Scan), Dynamic Scan,Cine Imaging and Cardiac tagging.]
- Fluid Visualization
- 2D / 3D Imaging
- MR Angiography / MR Vascular Imaging
- Blood Oxygenation Level Dependent (BOLD) imaging
- Perfusion / Diffusion Imaging
- Proton Spectroscopy

Prescription Use ✓ OR Over-The-Counter Use _____
(Part 21 CFR 801Subpart D) (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060003